

New Vaccine Recommendations

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Shot Smarts Immunization Conferences
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Advisory Committee on Immunization Practices (ACIP)

- **The recommendations to be discussed are primarily those of the ACIP**
 - **composed of 15 experts in clinical medicine and public health who are not government employees**
 - **provides guidance on the use of vaccines and other biologic products to the Department of Health and Human Resources, CDC, and the U.S. Public Health Service**

ACIP Recommendations

- **Recommendations approved by the Committee are just the first step**
- **Recommendations do not become official policy until**
 - **approved by the CDC Director, and**
 - **published in Morbidity and Mortality Weekly Report (MMWR)**

Topics for This Presentation

- **2017 Schedule**
- **Influenza**
- **Mumps**
- **Meningococcal**
- **HPV**

Comparison of 20th Century Annual Morbidity and Current Morbidity: Vaccine-Preventable Diseases

Disease	20th Century Annual Morbidity [†]	2016 Reported Cases ^{††}	Percent Decrease
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Measles	530,217	69	> 99%
Mumps	162,344	5,311	97%
Pertussis	200,752	15,737	92%
Polio (paralytic)	16,316	0	100%
Rubella	47,745	5	> 99%
Congenital Rubella Syndrome	152	1	99%
Tetanus	580	33	94%
<i>Haemophilus influenzae</i>	20,000	22*	> 99%

[†] JAMA. 2007;298(18):2155-2163

^{††} CDC. MMWR January 6, 2017/ 65(52);ND-924 – ND-941. (MMWR 2016 week 52 provisional data)

* *Haemophilus influenzae* type b (Hib) < 5 years of age. An additional 11 cases of Hib are estimated to have occurred among the 222 reports of Hi (< 5 years of age) with unknown serotype.

National Center for Immunization & Respiratory Diseases

Historical Comparisons of Vaccine-Preventable Disease Morbidity in the U.S.



Comparison of Pre-Vaccine Era Estimated Annual Morbidity with Current Estimate: Vaccine-Preventable Diseases

Disease	Pre-Vaccine Era Annual Estimate	2014 Estimate (unless otherwise specified)	Percent Decrease
Hepatitis A	117,333 [†]	3,500 [*]	97%
Hepatitis B (acute)	66,232 [†]	19,800 [*]	70%
Pneumococcus (invasive)			
all ages	63,067 [†]	28,000 [#]	56%
< 5 years of age	16,069 [†]	1,700 ^{##}	89%
Rotavirus (hospitalizations, < 3 years of age)	62,500 ^{††}	11,250 ^{###}	82%
Varicella	4,085,120 [†]	151,149 ^{####}	96%

[†] JAMA. 2007;298(18):2155-2163

^{††} CDC. MMWR. February 6, 2009 / 58(RR02);1-25

^{*} CDC. Viral Hepatitis Surveillance - United States, 2013

[#] CDC, Active Bacterial Core Surveillance Provisional Report; *S. pneumoniae* 2014

^{##} CDC. Unpublished, Active Bacterial Core Surveillance

^{###} New Vaccine Surveillance Network 2015 data (unpublished); U.S. rotavirus disease now has biennial pattern

^{####} CDC. Varicella Program 2014 data (unpublished)

National Center for Immunization & Respiratory Diseases

Historical Comparisons of Vaccine-Preventable Disease Morbidity in the U.S.



2017 Child and Adolescent Schedule

- **Highlighted visit at age 16 years**
- **Live attenuated influenza vaccine removed from the figure and footnote**
- **Hepatitis B footnote – birth dose should be administered within 24 hours of birth (previously “before hospital discharge”)**
- **MenACWY recommended for HIV infected children and adolescents**
- **2-dose HPV schedule**
- **2 dose MenB (Trumenba) schedule**

General Best Practices Guidelines for Immunization - 2017

- **Timing and Spacing of Immunobiologics**
- **Contraindications and Precautions**
- **Preventing and Managing Adverse Reactions**
- **Vaccine Administration**
- **Storage and Handling of Immunobiologics**
- **Altered Immunocompetence**
- **Special Situations**
- **Vaccination Records**
- **Vaccination Programs**
- **Vaccine Information Sources**

Posted April 20, 2017

www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Influenza Current Season Surveillance

- **Most circulating strains are A strains and predominantly H3N2**
- **Influenza B also circulating**
- **Vaccine strains are a good match for the virus circulating in US**
- **Moderate season**
- **May have peaked in week 8**
- **77 pediatric deaths (as of April 15)**

Influenza Virus 2016-2017

Virus	Circulating Virus	Vaccine Virus	
A/H1N1	A/California/7/2009 (100%)	A/California/7/2009	Match!
A/H3N2	A/Hong Kong/4801/2014 (98%)	A/Hong Kong/4801/2014	Match!
B/Victoria	B/Brisbane/60/2008 (92%)	B/Brisbane/60/2008	Match!
B/Yamagata	B/Phuket/3073/2013 (100%)	B/Phuket/3073/2013	Match!

www.cdc.gov/flu/weekly/index.htm, week ending April 8, 2017

Interim Influenza Vaccine Effectiveness Results for the 2016-2017 Season

- **Interim results indicate VE of 48% against any medically-attended influenza***
 - **43% for A/H3N2**
 - **73% for B/Yamagata**
 - **Similar to previous seasons when vaccine was well-matched to circulating influenza viruses**
- **End-of-season VE estimates may differ from interim estimates**

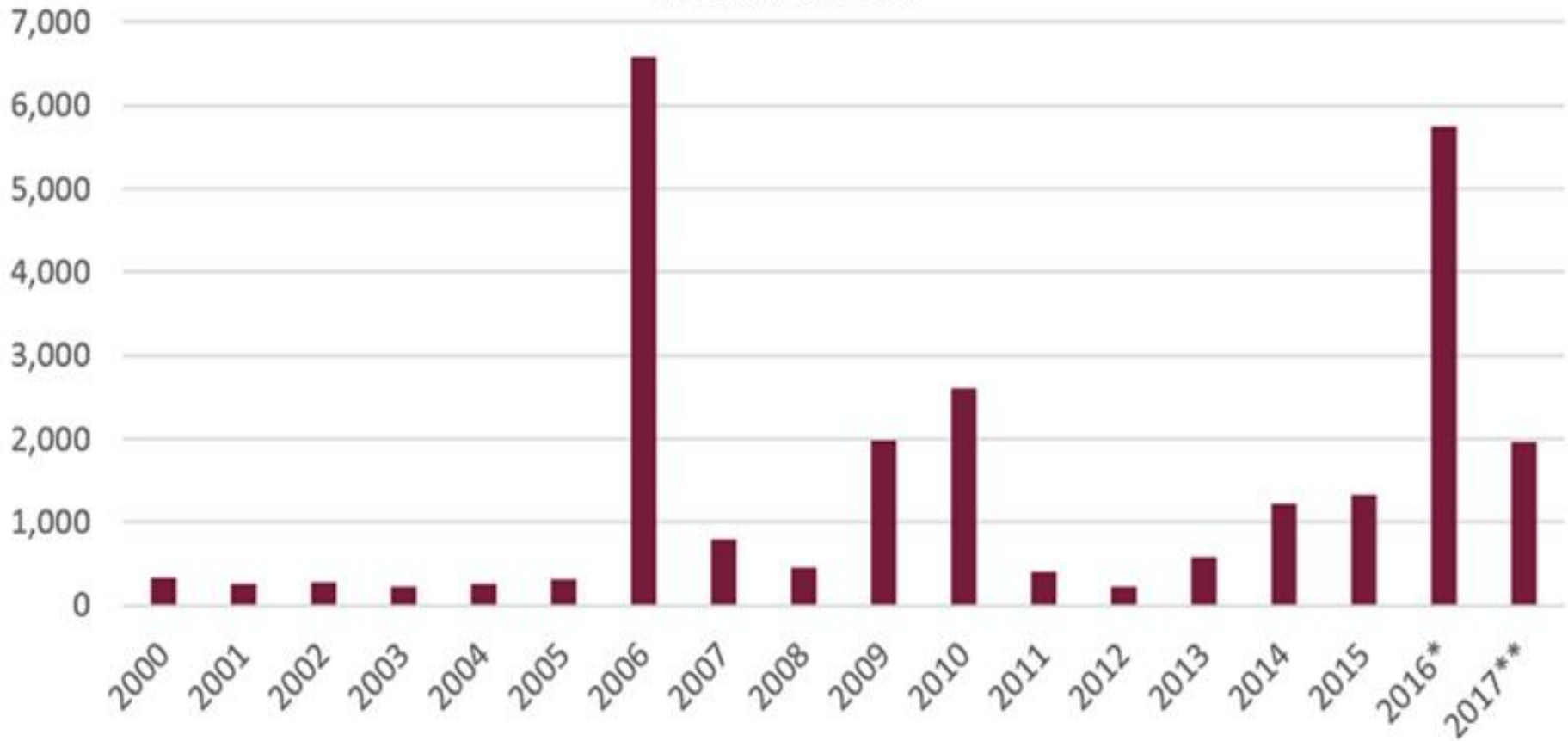
***through February 4, 2017. CDC Flu VE Network. No estimate for A/H1N1 or B/Victoria because of small numbers. *MMWR* 2017;66:167-71.**

LAIV Influenza Vaccine Updates ACIP Meeting, February 2017

- **The manufacturer is uncertain why effectiveness was low in 2013-14 and 2015-16**
- **There was no discussion of possible recommendations for next influenza season**
- **LAIV is not likely to be recommended for the 2017-2018 season**
- **ACIP will vote on 2017-2018 recommendations during their June meeting**

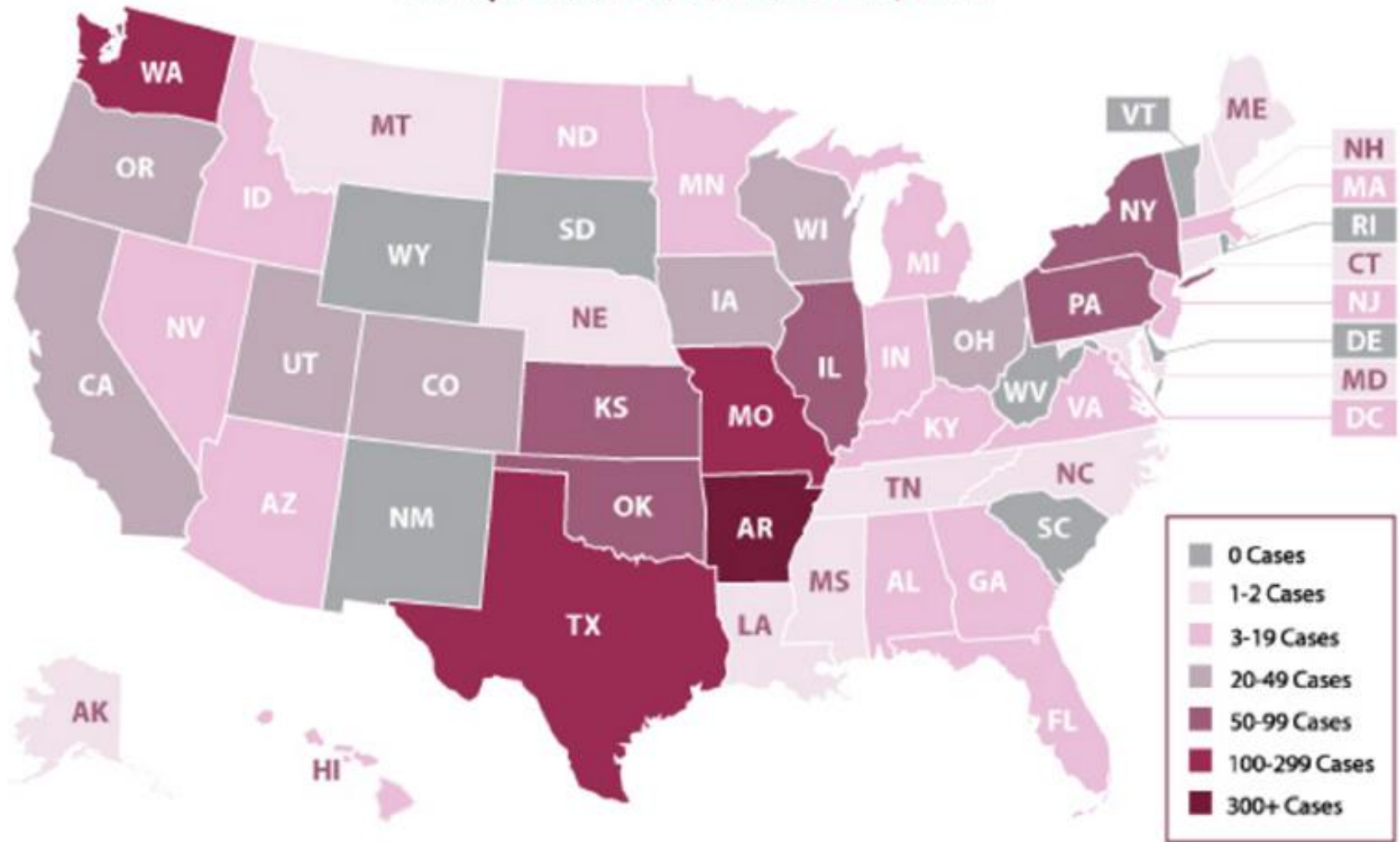
Mumps Cases in U.S., by Year

as of March 25, 2017



www.cdc.gov/mumps/outbreaks.html

Mumps Cases as of March 25, 2017



www.cdc.gov/mumps/outbreaks.html

Mumps and MMR Vaccine

- Mumps outbreaks can occur any time of year
- A major factor contributing to outbreaks is being in a crowded environment, such as attending the same class, playing on the same sports team, or living in a dormitory with a person who has mumps
- Two doses of MMR are 88% effective at protecting against mumps (range: 66 to 95%)
- One dose is 78% effective (range: 49% to 92%)

Mumps Epidemiology

- **Mumps vaccine has reduced disease by 97%**
- **Most recent cases are in fully vaccinated college students**
- **Mumps vaccine strain is effective against circulating mumps virus strain**
- **2-dose schedule may be sufficient for general population**
- **Third doses may be offered in outbreaks**
- **Benefit of third dose in general population needs to be assessed**

Discussion at ACIP meeting, February 23, 2017

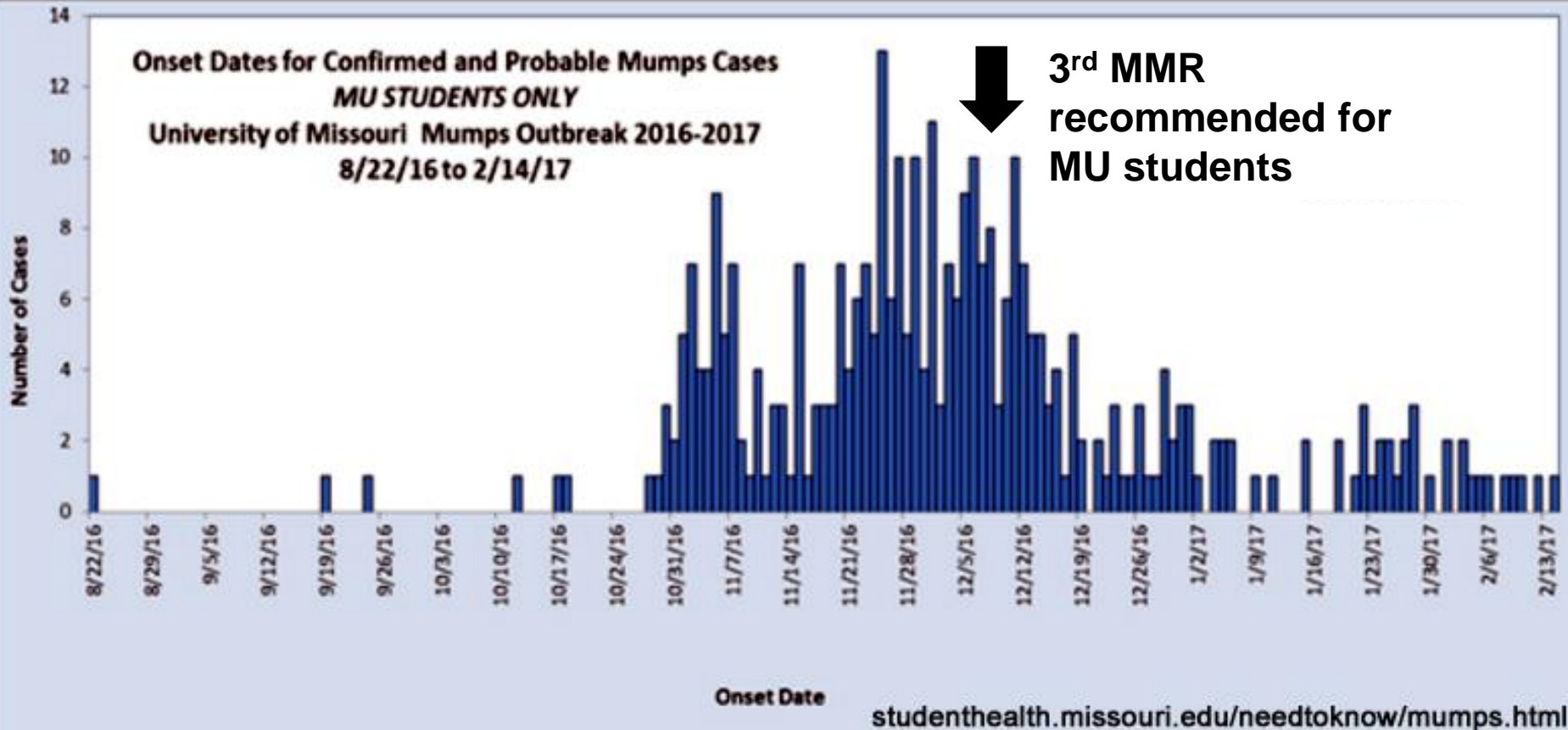
Example: Mumps in Missouri

- **From August 8, 2016 through March 8, 2017 there were 521 confirmed and probable cases**
- **Largest outbreak on the University of Missouri-Columbia campus**
 - **365 confirmed and probably cases since August 2016**
 - **All had received 2 doses of MMR**
 - **3rd MMR recommended**
- **Cases reported from other college campuses**

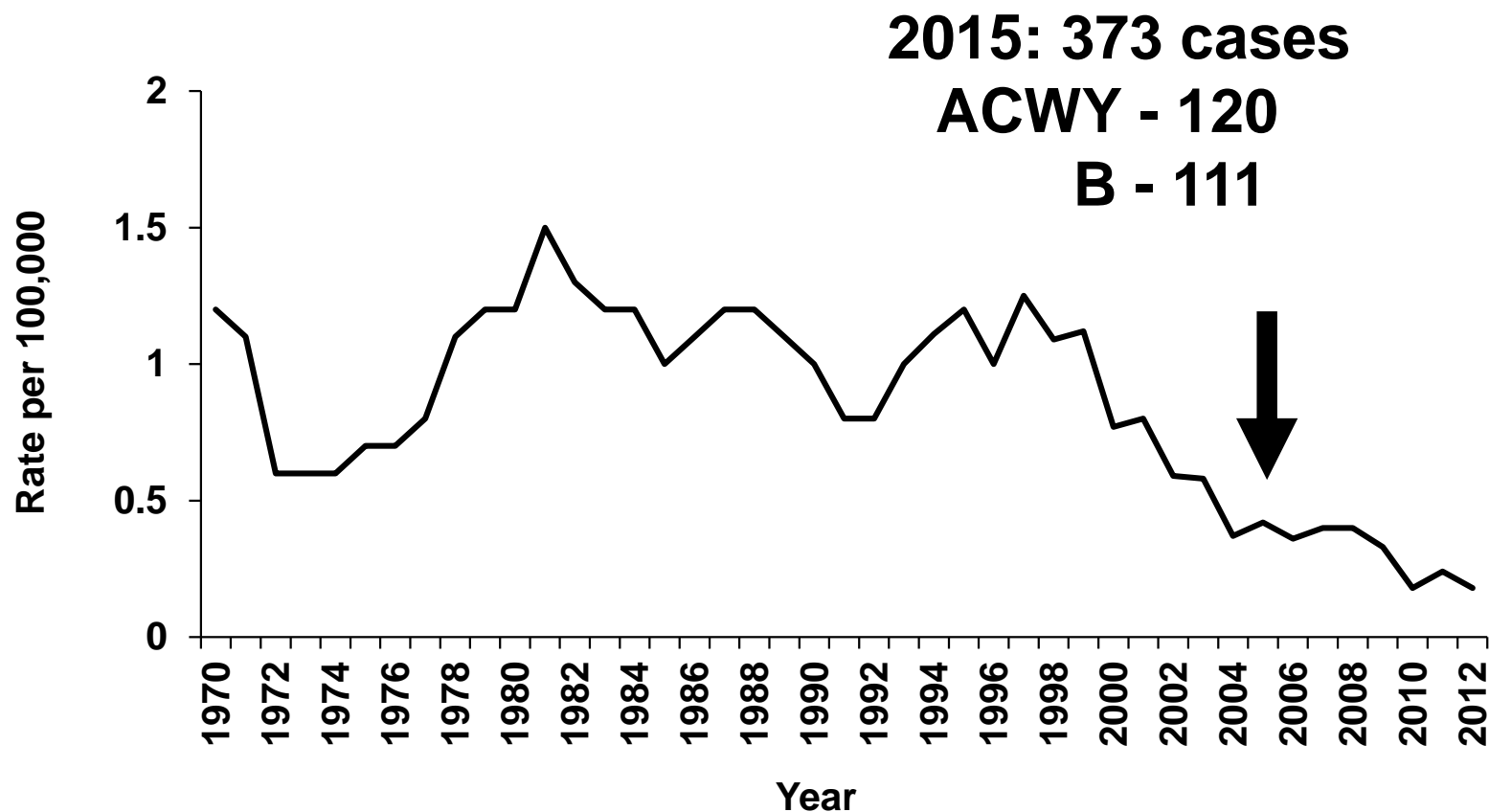
Onset Dates for Confirmed and Probable Mumps Cases
MU STUDENTS ONLY
University of Missouri Mumps Outbreak 2016-2017
8/22/16 to 2/14/17



3rd MMR
recommended for
MU students

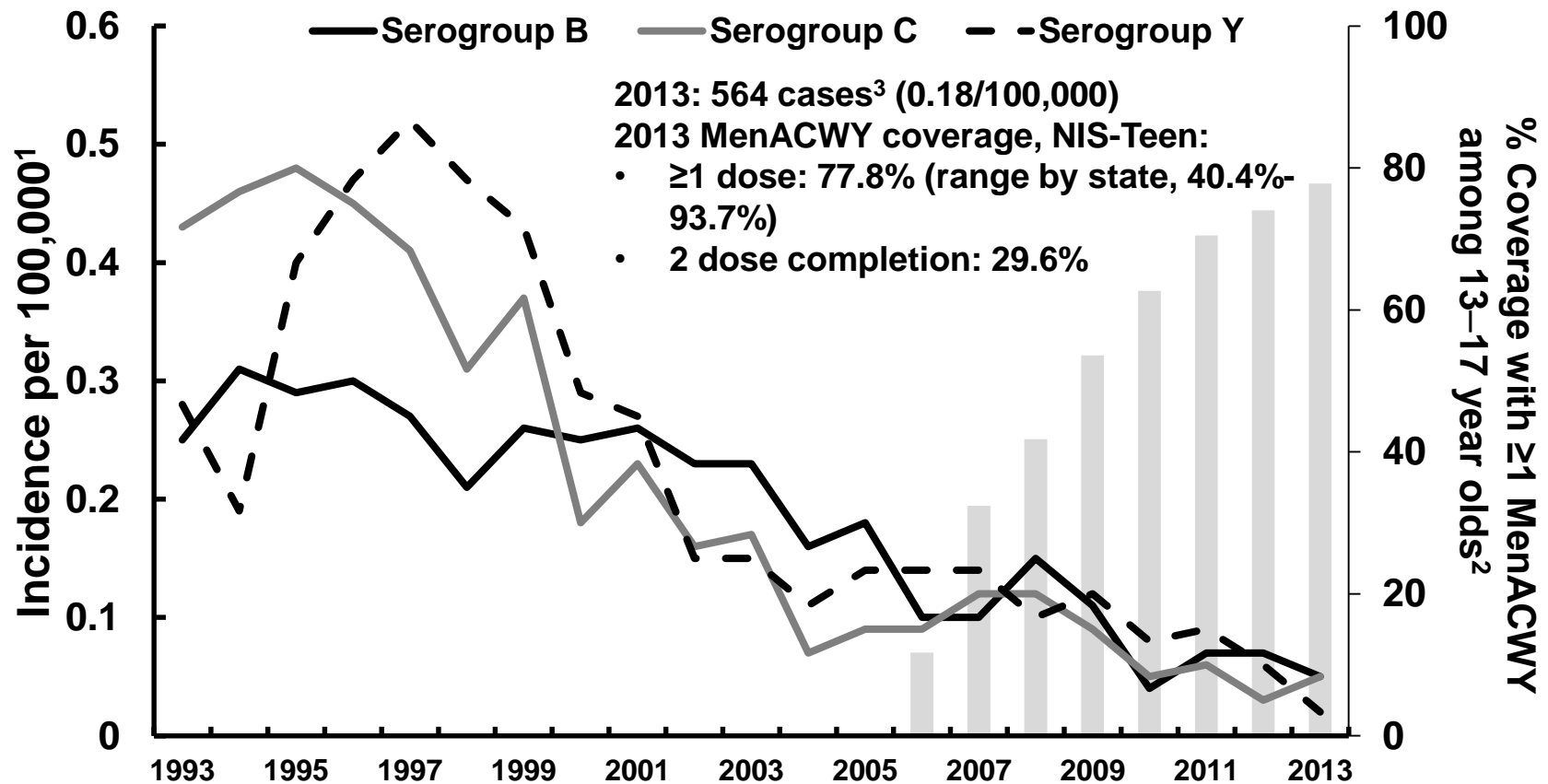


Meningococcal Disease Incidence, United States, 1970-2012



1970-1996 NNDSS data, 1997-2011 ABCs data estimated to U.S. population with 18% correction for under reporting. In 2010, estimated case counts from ABCs were lower than cases reported to NNDSS and may not be representative

Meningococcal Incidence in All Ages by Serogroup and Adolescent MenACWY Vaccine Coverage, 1993–2013



Source: Active Bacterial Core surveillance (ABCs) cases from 1993-2013 estimated to the U.S. population with 18% correction for nonculture confirmed cases. In 2010, estimated case counts from ABCs were lower than cases reported to the National Notifiable Diseases Surveillance System (NNDSS) and might not be representative.

²National Immunization Survey-Teen; 2006-2013.

³NNDSS 2013 final case count

The Expanding Universe of Meningococcal Vaccine

- **Meningococcal polysaccharide vaccine (MPSV4)**
 - first licensed in 1974
 - discontinued in 2017
- **Meningococcal conjugate vaccines (MenACWY)**
 - first licensed in 2005
- **Meningococcal B vaccines (MenB)**
 - first licensed in 2014

MenACWY Vaccines

- **Approved by the Food and Drug Administration based on serologic non-inferiority compared to meningococcal polysaccharide vaccine**
- **Menactra**
 - **approved for persons 9 months through 55 years***
- **Menveo**
 - **approved for persons 2 months through 55 years***

***may be used off-label in persons 56 years and older. *MMWR* 2013;62(RR-2):15**

MenACWY Routine Recommendations

Age at first dose	Booster dose
11-12 years	16 years*
13-15 years	16-18 years*
16-18 years	No

- Not routinely recommended for person age 19 years or older who are not at increased risk

*off-label recommendation. *MMWR* 2013;62(RR-2):1-28

Second Dose MenACWY Coverage is Suboptimal

- **First dose coverage at 81% among adolescents 13-17 years of age**
- **Only 33% for booster dose among 17 year-olds who received a first dose before age 16**
- **Opportunities to vaccinate are often missed**
- **Consider every opportunity to vaccinate**
 - **acute care visits**
 - **well visits**
 - **sports and camp physicals**
 - **routine visits for chronic illness**
 - **visits for influenza vaccine**

MenACWY Second Dose

**Resources to help improve second dose
MenACWY coverage available at**



www.give2mcv4.org/

**A collaborative project between IAC and Sanofi
Pasteur**

Persons at Highest Risk of Meningococcal Disease or Suboptimal Vaccine Response

- **Complement deficiency**
 - very high antibody titer required to compensate for complement deficiency
- **Asplenia**
 - evidence of suboptimal response
- **HIV infection**
- **Single dose primary series may not be sufficient to confer protection for persons with these high-risk conditions**

MenACWY Recommendations for HIV-infected Persons

- **Accumulating evidence indicates that HIV infection increases the risk of invasive meningococcal disease**
- **ACIP now recommends routine MenACWY vaccination for all HIV-infected persons age 2 months and older**
- **Number of doses depends on age**
 - **2-4 doses for children younger than 2 years**
 - **Persons 2 years and older should receive 2 doses separated by 8 weeks**

MenACWY Recommendations for High Risk Groups

- **Administer 2 doses* of MenACWY at least 8 weeks apart to persons 2 years and older with persistent complement component deficiency, anatomic or functional asplenia, or HIV infection and 1 dose every 5 years* thereafter**

*** off-label recommendations. *MMWR* 2013;62(RR-2):1-28**

MenACWY Recommendations – College Students

- **Recommended for persons age 19 through 21 who are first-year college students AND living in a resident hall**
 - **1 dose if previously unvaccinated**
 - **booster dose if previous dose given at age younger than 16 years**

Frequently Asked Question

- **Sanofi is discontinuing the production of Menomune (MPSV4) this year. I administer a lot of travel vaccine doses. Should I now give MenACWY (Menactra or Menveo) off-label to travelers age 56 years and older?**

In its 2013 meningococcal recommendations, ACIP recommended off-label use of MenACWY vaccine (not MPSV4) for people age 56 years or older who were vaccinated previously with MenACWY and are recommended for revaccination or for whom multiple doses are anticipated (for example, people with asplenia and microbiologists). The situation of unavailability of MPSV4 is not addressed, but the use of MenACWY vaccine is appropriate when MPSV4 is not available.

Groups at Increased Risk for Meningococcal B Disease

- **High-risk medical conditions:**
 - **persistent complement component deficiencies**
 - **functional or anatomic asplenia**
- **Certain microbiologists**
- **Populations at risk during an outbreak**
- **NOT at increased risk: international travelers, first year college students, people with HIV infection**

Meningococcal Serogroup B Vaccines

- **Trumenba (Pfizer)**
 - **Licensed by FDA on October 29, 2014**
 - **Approved for 10 through 25 years of age**
 - **2 components**
 - **2 or 3 dose series**
- **Bexsero (Novartis)**
 - **Licensed by FDA on January 23, 2015**
 - **Approved for 10 through 25 years of age**
 - **4 components**
 - **2 dose series**

Information from manufacturer's package inserts

ACIP Recommendations for Meningococcal B Vaccine of High Risk Persons

- **Certain persons 10 years of age or older* who are at increased risk for meningococcal disease should receive MenB vaccine**
 - **persistent complement component deficiency**
 - **anatomic or functional asplenia**
 - **risk in a serogroup B meningococcal disease outbreak**
 - **certain microbiologists**
- **MenB vaccines are included in VFC**
- **NOT routinely recommended for college students, international travelers, HIV+ persons**

***off-label for persons 26 years and older. *MMWR* 2015;64:608-12**

Revised MenB Vaccine Schedule Recommendations*

- **For persons at increased risk of meningococcal B disease**
 - 2 doses of Bexsero (1 month apart) or
 - 3 doses of Trumenba (0, 2, 6 months)
- **For persons not at increased risk of meningococcal B disease**
 - 2 doses of Bexsero (1 month apart) or
 - 2 doses of Trumenba (6 months apart)

***published in the 2017 schedule, February 7, 2017**

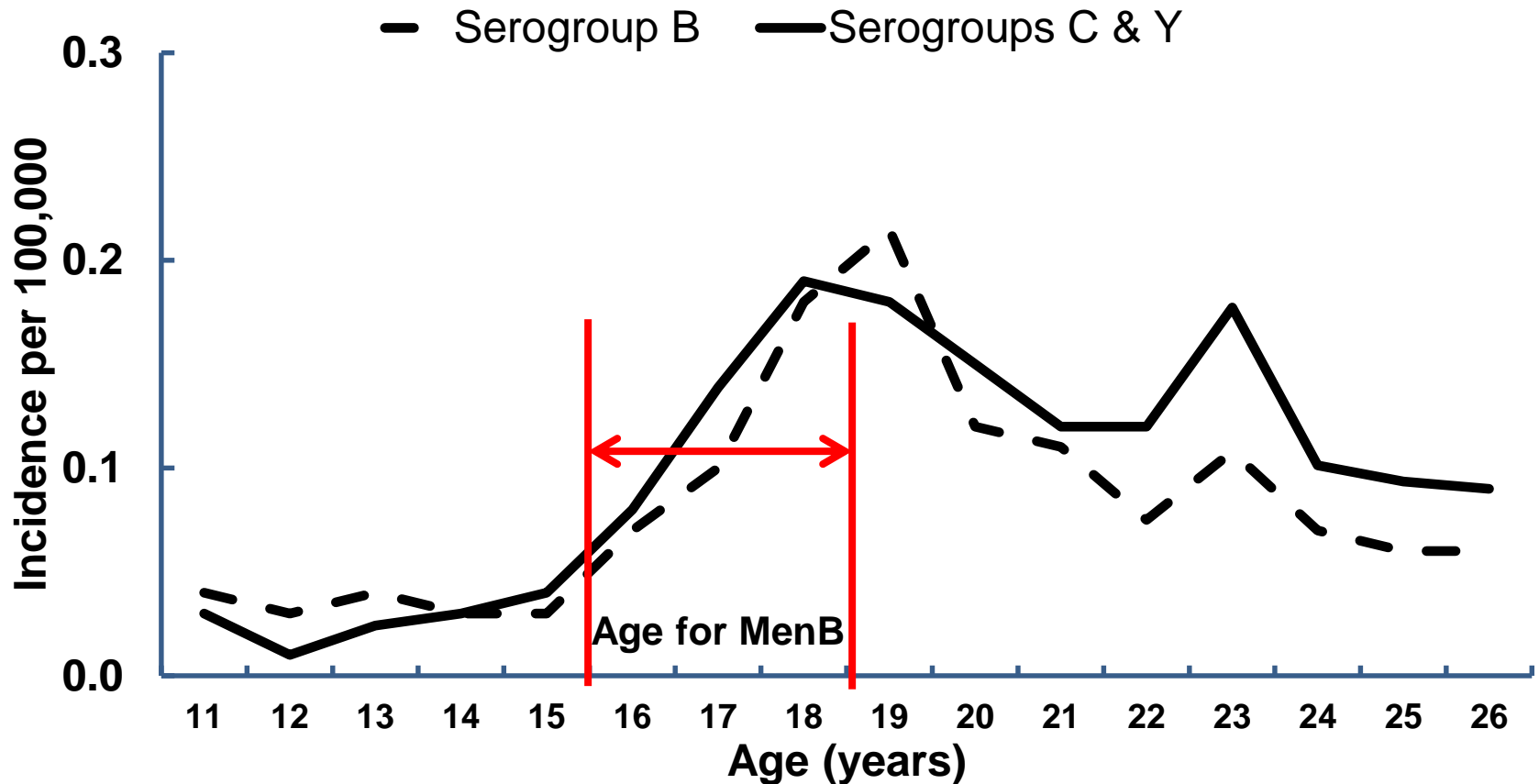
ACIP Recommendations for Meningococcal B Vaccine

- **Approximately 15 to 29 cases and two to five deaths could be prevented annually with a routine adolescent MenB vaccination program administered at age 11, 16, or 18 years**
- **A recommendation for college students only is estimated to prevent approximately nine cases and one death annually**

ACIP Recommendations for Meningococcal B Vaccine

- **A MenB vaccine series *may be administered* to adolescents and young adults aged 16 through 23 years to provide short-term protection against most strains of serogroup B meningococcal disease (Category B recommendation)**
- **The preferred age for MenB vaccination is 16–18 years**
- **Vaccines with a Category B recommendation are included in the VFC program and ACA insurance programs**

Meningococcal Incidence in Adolescents and Young Adults by Serogroup, 2009–2013



NNDSS data supplemented with additional serogroup data from ABCs and state health departments. Unknown serogroup (19%) and other serogroups (8%) excluded

ACIP Recommendations for Meningococcal B Vaccine

- **The two MenB vaccines are NOT interchangeable**
- **The same vaccine *must* be used for all doses**
- **Minimum intervals between doses have not been defined – use routine schedule only**
- **Need for booster dose(s) unknown – not recommended at this time**
- **MenB vaccines can be given at the same time as other vaccines including MenACWY**

HPV Infection Is the Most Common Sexually Transmitted Disease in the United States

- **Approximately 79 million Americans are currently infected**
- **14 million new infections/year in the United States**
 - **about half of these new infections occur among persons 15-24 years of age**
- **Almost all sexually active men and women will be infected at some point in their lives**
- **Immunocompromised persons have higher rates of HPV acquisition and progression to disease**

Average Annual HPV-Attributable Cancers in the United States, 2008-2012

- 38,793 HPV-associated cancers diagnosed annually
 - 15,793 in men
 - 23,000 in women

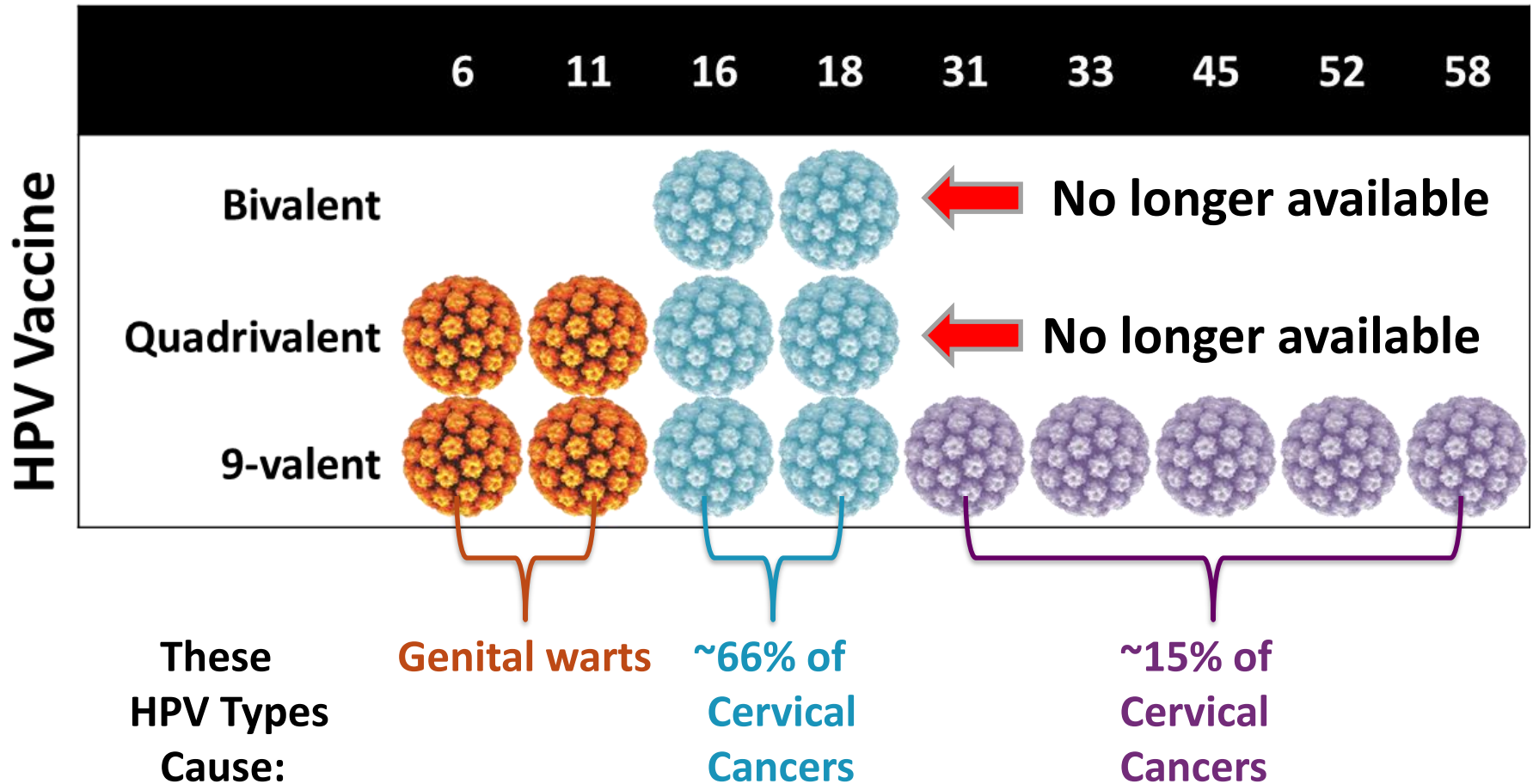
Site	Male	Female	Total Cancers
Cervix	0	11,771	11,771
Anus	1,750	3,200	5,010
Vagina	0	802	802
Oropharynx	12,638	3,100	15,738
Vulva	0	3,554	3,554
Penis	1,168	0	1,168

73% attributable to HPV strains included in the 9-valent vaccine

MMWR 2016;65 (No. 26):661-71

HPV Vaccine Comparison

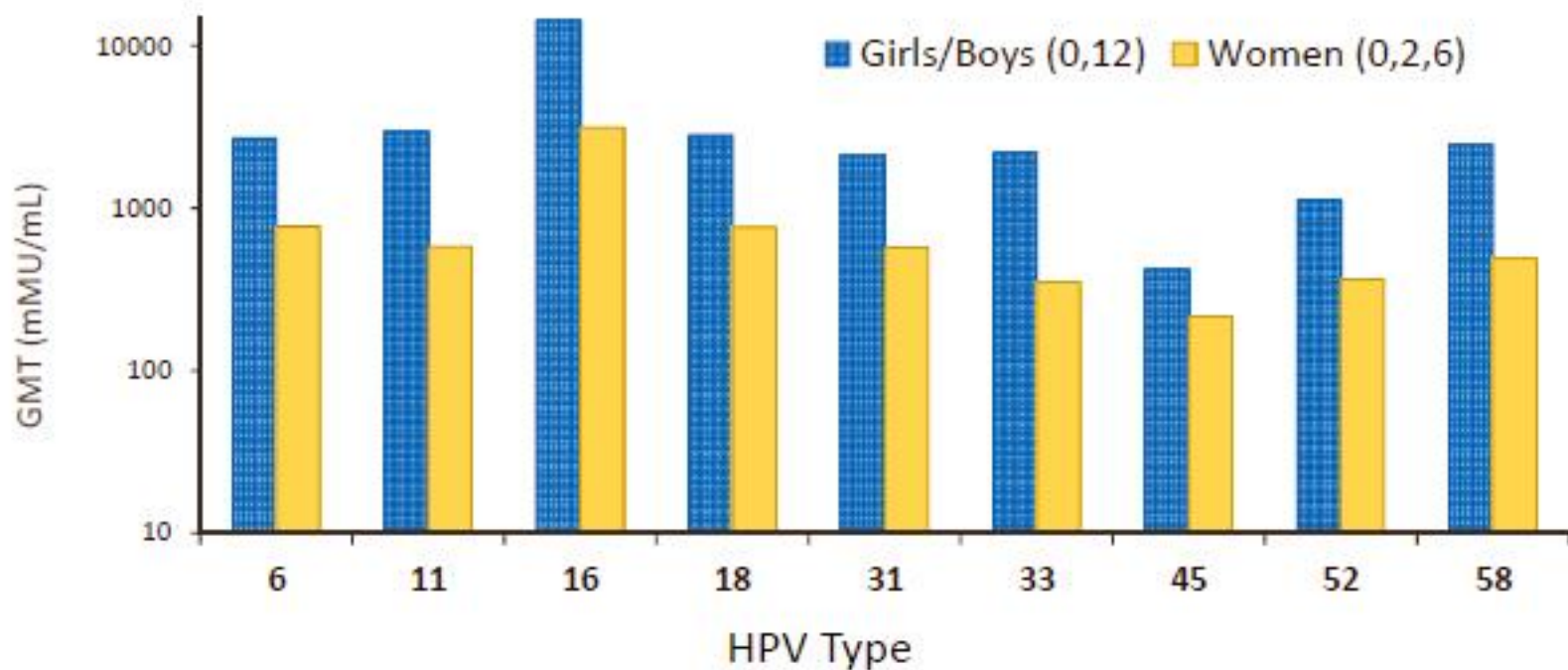
HPV Types Included in Vaccine



9vHPV 2-Dose Immunogenicity Trial

Non-inferior geometric mean antibody titers (GMT)

2-dose girls/boys age 9-14 years vs. 3-dose women age 16-26 years



Luxembourg, presented at February 2016 ACIP

Data from 1 month after the last dose

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf>

ACIP HPV 2-Dose Recommendations

- **A 2-dose schedule is recommended for persons beginning the HPV series before 15 years of age**
- **Doses must be separated by at least 5 months (recommended interval 6-12 months)**
- **If doses are separated by less than 5 months then 3 doses are recommended**
- **Persons beginning the series at 15 years or older or who are immunosuppressed should receive a 3-dose schedule**
- **2-dose schedule can be completed with any combination of HPV vaccines and is retroactive**

HPV Vaccine Special Populations

- **Children with a history of sexual abuse or assault**
 - **routine HPV vaccination beginning at age 9 years**
- **MSM**
 - **vaccination through age 26 years**
- **Transgender persons**
 - **vaccination through age 26 years**

HPV Vaccine Medical Conditions

- **Primary or secondary immunocompromising conditions**
 - **3 dose series through age 26 years**
- **Examples: B-lymphocyte antibody deficiency, T-lymphocyte complete or partial defects, HIV infection, malignant neoplasm, transplantation, autoimmune disease, immunosuppressive therapy**
- **Does NOT include asplenia, chronic granulomatous disease, chronic liver, lung or renal disease, cochlear implant, complement deficiency, diabetes, heart disease or sickle cell disease**

ACIP Recommendations: Timing of the 3-dose Series

- **9vHPV should be given in a 3-dose schedule for ages 15 through 26 years***
- **Usual schedule is 0, 1-2, 6 months**
- **Minimum intervals**
 - **4 weeks between the first and second doses**
 - **12 weeks between the second and third doses, and**
 - **5 months between the first and third doses**
- **If the vaccine schedule is interrupted, the series does not need to be restarted**

***also immunosuppressed persons. *MMWR* 2016;65(No. 49):1405-8**

9vHPV ACIP Recommendations

- **ACIP has declined to make any recommendation regarding revaccination with 9vHPV for persons who already completed a series of 2vHPV or 4vHPV**
- **Clinicians are free to revaccinate with 9vHPV but VFC will not cover additional doses and insurance plans may not pay for these doses**

HPV Vaccine

Contraindications and Precautions

- **Contraindications**
 - **Severe allergic reaction to a vaccine component or following a prior dose**
 - **Pregnancy**
- **Precautions**
 - **Moderate or severe acute illnesses (defer until symptoms improve)**

HPV Vaccination and the Risk of Adverse Pregnancy Outcomes

- **Cohort of women in Denmark who had a pregnancy ending between October 1, 2006 and November 30, 2013**
- **Compared outcomes of women who received 4vHPV during pregnancy to those who did not**
- **No significantly higher risk of**
 - **major birth defects**
 - **spontaneous abortion**
 - **preterm birth**
 - **low birth weight**
 - **small size for gestational age**
 - **stillbirth**

Scheller NM et al. *N Engl J Med* 2017;376:1223-33. March 30, 2017

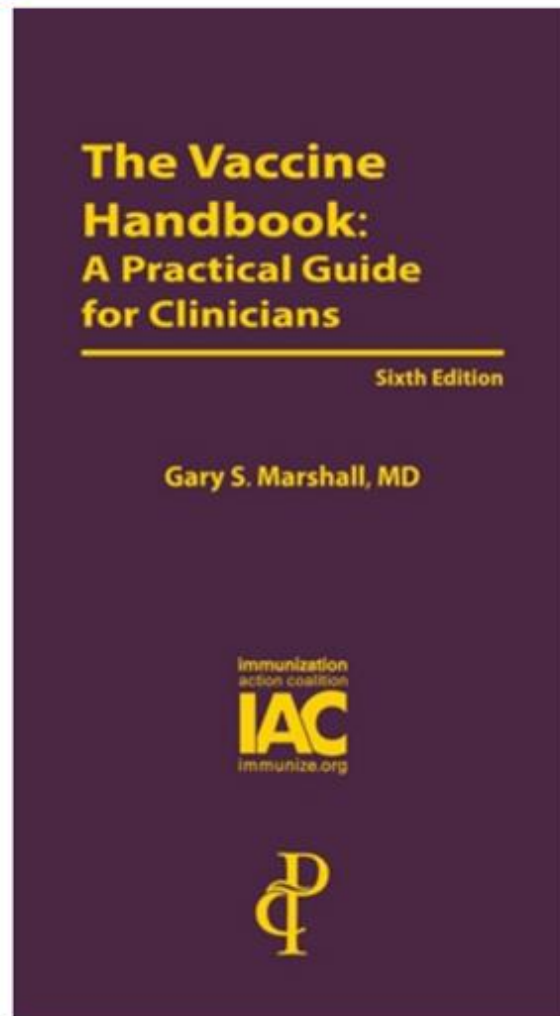
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The Vaccine Handbook: A Practical Guide for Clinicians ("The Purple Book")



Product Number: R2012

Date Published: April 2017

Description:

The 6th edition of *The Vaccine Handbook: A Practical Guide for Clinicians* ("The Purple Book") is considered a vital source of practical, up-to-date information for vaccine providers and educators. Now printed in color and updated with the latest vaccine information through early 2017, the Purple Book draws together the latest vaccine science and guidance into a concise, user-friendly, practical resource for the private office, public health clinic, academic medical center, and hospital.

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The app is fully searchable, allows for bookmarking, highlighting and annotation, and contains hyperlinks to valuable content from nonprofit and governmental sources.

<https://itunes.apple.com/us/app/the-vaccine-handbook-app/>

Immunization Action Coalition Resources

- **Websites**

- www.immunize.org (for HCP)
- www.vaccineinformation.org (for the public)
- www.izcoalitions.org (for coalitions)
- www.izsummitpartners.org (adult immunization)

- **Publications – Needle Tips, Vaccinate Adults, IAC Express**

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